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DETAILED ACTION

Election/Restrictions

1. Claims 19-20, 24-26 are cancelled.

2. Restriction is required under 35 U.S.C. 121 and 372.

Part I: Types of inventions

Group I, claim(s) 1 and 4-11, drawn to a method of screening for therapeutic agents by detecting binding to GPR85.

Group II, claim(s) 2, drawn to a method of screening for therapeutic agents by determining activity of GPR85.

Group III, claim(s) 3, drawn to a method of screening for therapeutic agents by determining activity of GPR85 in the presence of regulator.

Group IV, claim(s) 12-17, drawn to a method of screening for therapeutic agents by detecting binding to GPR85 polynucleotide.

Group V, claim(s) 18, drawn to a method of diagnosing a disease.

Group VI, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising a small molecule.

Group VII, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising an RNA molecule.

Group VIII, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising an antisense oligonucleotide.

Group IX, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising a polypeptide.

Group X, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising an antibody.

Group XI, claim(s) 21, drawn to a pharmaceutical composition for the treatment of disease comprising a ribozyme.

Group XII, claim(s) 22, drawn to a pharmaceutical composition for the treatment of disease comprising a GPR85 polynucleotide.

Group XIII, claim(s) 23, drawn to a pharmaceutical composition for the treatment of disease comprising a GPR85 polypeptide.

The inventions listed as Groups I-XIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Group I is drawn to a method of screening for therapeutic agents by detecting binding to GPR85. Pursuant 37 CFR 1.475(d), these claims are considered by the ISA/US to constitute the main invention, and none of the related groups II-XIII correspond to the main invention.

The method of Group I do not share the same special technical feature as the products of group IV-XIII in any one of the pairing, because any one of the product of group IV-XIII is not produced by the method of group I, and each defines a separate invention over the art.

The products of Group IV-XIII do not share a special technical feature because the products have materially different structures and functions.

The methods of Group I-IV do not share a special technical feature because the methods have different steps and use materially different products.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

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and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

The inventions have acquired a separate status in the art in view of their different classification, a separate status in the art when they are classfieable together, and a different field of search.

Part II: disorders

Furthermore, restriction to one of the following inventions is required under 35 USC 121:

The inventions as they pertain to one disorders encompassed by the claims.

This is a further requirement for restriction into separately patentable groups.

Applicant must elect one disorder in order to be fully responsive. Because each disorder requires a unique search of the disorder in the literature databases and undue search burden would be imposed on the examiner if all of the disorder were examined on one patent application.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

3. The examiner has required restriction between product and process claims.
Where applicant elects claims directed to the product, and the product claims are
subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Pak/ Primary Examiner, Art Unit